

(12) STANDARD PATENT

(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 2003277983 B2

(54) Title
Heart assist device utilising aortic deformation

(51) International Patent Classification(s)
A61M 1/10 (2006.01) **A61M 1/12** (2006.01)

(21) Application No: **2003277983** (22) Date of Filing: **2003.11.06**

(87) WIPO No: **WO04/045677**

(30) Priority Data

(31) Number **2002952691** (32) Date **2002.11.15** (33) Country **AU**

(43) Publication Date: **2004.06.15**
(43) Publication Journal Date: **2004.07.15**
(44) Accepted Journal Date: **2008.06.26**

(71) Applicant(s)
Sunshine Heart Company Pty Ltd

(72) Inventor(s)
Peters, William Suttle;Watterson, Peter Andrew;Miller, Scott Hugh

(74) Agent / Attorney
Spruson & Ferguson, Level 35 St Martins Tower 31 Market Street, Sydney, NSW, 2000

(56) Related Art
US 4583523
US 6045496
US 4630597
WO 0224254
WO 0224255
US 6030336
WO 0076288
US 4051840
US 6471633
US 4979936

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
3 June 2004 (03.06.2004)

PCT

(10) International Publication Number
WO 2004/045677 A1

(51) International Patent Classification⁷:

A61M 1/10

(21) International Application Number:

PCT/AU2003/001458

(22) International Filing Date:

6 November 2003 (06.11.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

2002952691 15 November 2002 (15.11.2002) AU

(71) Applicant (for all designated States except US): SUNSHINE HEART COMPANY PTY LTD [AU/AU]; Top Floor, Unit 2, 10 Rockborough Road, Frenchs Forest, NSW 2086 (AU).

(72) Inventors; and

(75) Inventors/Applicants (for US only): PETERS, William, Suttle [NZ/NZ]; 93 Bassett Road, Remuera, Auckland 1005 (NZ). MILLER, Scott, Hugh [US/AU]; 35/10 Darley Road, Manly, NSW 2095 (AU).

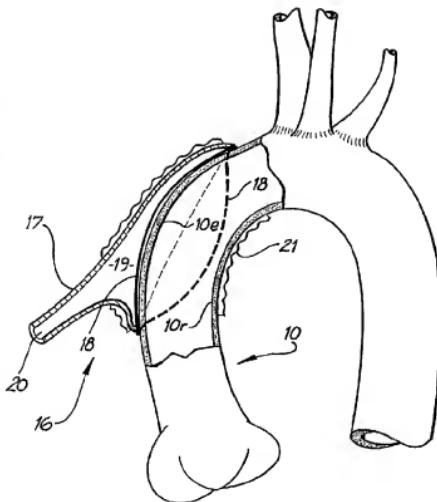
(74) Agent: SPRUSON & FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, IU, ID, IL, IN, IS, JE, KG, KE, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PI, PL, PT, RO, RU, SC, SD, SE, SG, SK, SI, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: HEART ASSIST DEVICE UTILISING AORTIC DEFORMATION



(57) Abstract: A device (16) for assisting the functioning of the heart of a patient. The device (16) includes an aortic compression means (18) adapted, when actuated, to compress an aorta (10) and motive means to periodically actuate, and de-actuate, the aortic compression means (18) in counter-pulsation with the patient's heart rhythm. The aortic compression means (18) is adapted to compress only a portion of the circumference of the aorta (10).

WO 2004/045677 A1



European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE,
SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

HEART ASSIST DEVICE UTILISING AORTIC DEFORMATION

FIELD OF THE INVENTION

5

The present invention relates generally to counterpulsation heart assist devices, systems and methods and, more particularly, to heart assist devices utilising aortic deformation and/or aortic resection.

BACKGROUND OF THE INVENTION

10

The concept of providing counter-pulsation support for the failing heart has been known since the pioneering work of Kantrowitz. Counter-pulsation causes displacement of a volume of a patient's blood in the patient's aorta while the patient's heart is dilating in diastole and after the aortic valve has closed. This assists to move blood around the patient's peripheral vasculature as well as into the coronary arteries. The timed volume displacement in the aorta on the blood within the aorta just in advance of systolic ejection of blood from the heart reduces the afterload on the heart, by causing a transient low pressure above the aortic valve.

It is known from the use of counter-pulsation in Intra-Aortic Blood Pumps (IABPs) that counter-pulsation can provide short term support for the failing heart. These devices require a balloon to be inserted percutaneously into the descending aorta. The balloon is inflated and deflated in counter-pulsation with the heart by the transmission of a gas, usually helium, between the balloon and a bedside console. These devices suffer from the problem that there is a high risk of thrombo-embolism if the balloon remains in the vasculature for a prolonged period, which can lead to ischemic leg complications.

There have been a number of attempts to provide counter-pulsation support for the failing heart by applying counter-pulsation pressure to the outside of the aorta. These

proposals are contained in the following patent specifications:

PCT 99/04833

USA 4,014,318

USA 4,583,523

5 USA 4,979,936

USA 6,030,336

USA 6,045,496

A similar arrangement is described by Furman, New York Journal of Medicine, August 1, 1970, pp 1964-1969. In all of these arrangements means are provided to surround, or at 10 least substantially surround, the aorta and to apply a squeezing pressure substantially uniformly around the circumference of the aorta. The present inventors have found that there are substantial advantages if the counter-pulsation pressure is applied to only a part of the circumference of the aorta.

It is also known to resect a part of the aorta for the purpose of inserting a patch or 15 other graft into the aorta and to cause such patch or graft to counterpart. Such a system is described in the following patent specifications:

PCT 01/13974

USA 4,630,597

20 The device described in these specifications is for insertion into the descending aorta which is straight. There is no suggestion of how to deal with the more complex issues that arise in placing the device into the ascending aorta which is curved along its length.

OBJECT OF THE INVENTION

It would be desirable to have a heart assist device, which may or may not be blood contacting, that could provide assistance to the heart function with reduced risk to the patient and/or of device malfunction than prior art devices.

5

SUMMARY OF THE INVENTION

In a first aspect, the present invention provides a method of providing counter-pulsation heart assistance, the method comprising:

installing a heart assist device on the ascending aorta of a patient, said heart assist device being capable of exerting compressive force on the outer wall of the aorta and extending around a portion of the circumference of the aorta; and

causing said heart assist device to cyclically compress a portion of the circumference of the aorta, such that the aorta is caused to flex along a continuous line which increases in length as the compressive force applied to the aorta increases. The heart assist device is a non-inflatable mechanical device.

The mechanical device is preferably rigid. The said rigid device is preferably adapted to move along a linear path or along an arcuate path. The rigid device preferably moves at a right angle to the axis of the aorta if the portion of the artery contacted by the rigid device is straight or at a right angle to a tangent of a curved portion if the portion of the aorta contacted by the rigid device is curved.

The heart assist device preferably defines a membrane which in whole or in part comprises a chamber, said chamber being capable of being inflated and deflated, said chamber being configured such that when said chamber is deflated, the membrane is substantially smoothly curved, and said membrane having a concave surface when it is deflated such that the concave surface faces inwardly toward the lumen of the aorta. In one form, the membrane is substantially inelastic. In another form, the membrane is substantially elastic.

Preferably the radially outer surface of the aorta is compressed. The aorta is preferably compressed to create a curved ovate depression.

The membrane is preferably sealingly attached to a shell such that said chamber comprises the space between said shell and said membrane.

The aorta is preferably compressed through not more than 180 degrees of its circumference. The aorta is preferably compressed through not more than 160 degrees of its circumference. The aorta is preferably compressed through not more than 140 degrees of its circumference. The aorta is preferably compressed through 100 to 140 degrees of its circumference.

When fully invaginated by said heart assist device, the invaginated portion of said wall is preferably the mirror image of said wall when no compressive force is exerted.

5 A layer of material is preferably provided between said heart assist device and said wall.

The aorta is preferably compressed substantially without bunching or stretching.

10 The compressive force preferably causes said aorta to flex along a continuous line which increases in length as the pressure increases. The line preferably has the shape of a conic section. The compressive force is preferably exerted in a direction normal to a tangent of the radially outer surface of the longitudinal curve in the aorta. The compressive force preferably causes said aorta to be progressively deformed along a line in a plane running through said aorta, which plane moves radially inwardly.

Access to the ascending aorta is preferably achieved by a sternotomy.

15 In a second aspect, the present invention provides a method of providing counter-pulsation heart assistance, the method comprising:

installing an inflatable heart assist device on the aorta of a patient, said heart assist device being capable of exerting compressive force on the outer wall of the aorta and extending around a portion of the circumference of the aorta;

20 periodically introducing fluid to inflate said heart assist device in synchrony with the diastolic period of the heart to reduce the interior volume of the aorta, such that the aorta is caused to flex along a continuous line which increases in length as the compressive force applied to the aorta increases;

deflating said heart assist device; and

25 alternating periods of inflation with periods of deflation to periodically deflate the heart assist device in synchrony with the commencement of the systolic period of the heart, thereby allowing the portion of the aorta adjacent to said heart assist device to periodically return to normal interior volume.

The heart assist device preferably comprises a patch. The patch is preferably provided with a flexible membrane sealingly attached to at least part of the interior of the patch thereby forming an inflatable space adjacent to the interior of the patch device which inflatable space is periodically inflated and deflated.

30 The heart assist device preferably comprises an inflatable member located adjacent to the outer wall of the aorta.

In a third aspect, the present invention provides a method of providing counter-pulsation heart assistance, the method comprising:

installing a heart assist device on the descending aorta of a patient, said heart assist device being capable of exerting compressive force on the outer wall of the aorta and extending around a portion of the circumference of the aorta; and

5 causing said heart assist device to cyclically compress a portion of the circumference of the aorta, such that the aorta is caused to flex along a continuous line which increases in length as the compressive force applied to the aorta increases.

The aorta is preferably compressed to produce a smoothly curved circular depression.

Access to the descending aorta is preferably achieved by a thoracotomy.

10 In a fourth aspect, the present invention provides a heart assist device which includes aorta deformation means to apply a counter-pulsation to an artery in the vasculature of a patient, characterized in that the deformation means applies a deforming force to the exterior of the artery such that the artery is caused to flex along a continuous line which increases in length as the counterpulsation pressure applied to the artery increases.

15 The line preferably has the shape of a conic section.

This page intentionally left blank.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

- Fig 1 is a cross sectional ventral view of the aorta of a patient with a first embodiment of a device for assisting the functioning of a heart;
- Fig 2 is a schematic lateral view of the device shown in Fig 1;
- Fig. 3 is a ventral view of the aorta of a patient showing a series of planes through the aorta in which lines of flexure of the aortic wall will lie during application of a deforming force to the aorta;
- 10 Fig. 4 is cross sectional view along line 4-4 through the aorta of Fig. 3 showing a sequence of shapes assumed by the aortic wall as it is deformed;
- Fig.5 is a part longitudinal cross-sectional view through the aorta of Fig. 3 along line 5-5 of Fig. 6, showing a sequence of shapes assumed by the aortic wall as it is deformed;
- 15 Fig 6 is a lateral view from the right side of the aorta of Fig. 3, showing a sequence of lines of flexure as the aorta is deformed;
- Fig. 7 is a schematic side view of an ascending aorta showing a resection line;
- Fig. 8 is a schematic side view of the aorta shown in Fig. 7 after resection of a portion of the aorta;
- 20 Fig. 9 is a schematic side view of another embodiment of a device for assisting the functioning of the heart with a withdrawn internal membrane;

Fig. 10 is a schematic side view of the device shown in Fig. 9 with an expanded membrane;

Fig. 11 is a schematic side view of the aorta shown in Fig. 8 after surgical attachment of the device shown in Figs. 9 and 10 with the membrane shown in withdrawn 5 and expanded positions;

Fig. 12 is a schematic cross sectional end view of the aorta and device shown in Fig. 11;

Fig. 13 is a schematic cross sectional view of an aorta of reduced size with a resected portion;

10 Fig. 14 is a cross sectional end view of the aorta of Figs. 13 and 15 after surgical attachment of a further embodiment of device for assisting in the functioning of the heart;

Fig. 15 is a schematic front view of the resected aorta shown in Fig. 13;

Fig. 16 is a schematic front view of the aorta and device shown in Fig. 15;

15 Fig 17 is a schematic side view of an ascending aorta showing an alternatively positioned resection line;

Fig 18 is a cross sectional ventral view of the aorta of a patient with a further embodiment of a device for assisting the functioning of a heart.

DETAILED DESCRIPTION OF THE PREFERRED

20

EMBODIMENTS

Fig. 1 is a schematic side view of an ascending aorta 10 and a heart assist device 16 in accordance with an embodiment of the invention. The device 16 has a relatively inelastic, preferably plastic, shell 17 and a flexible membrane 18 sealingly attached to the

periphery of the shell 17. The membrane 18 defines an inflatable space 19 between it and the interior of the shell 17. The shell 17 also has an inlet/outlet port 20 which is adapted for connection to a motive means that can periodically introduce, and withdraw, a fluid (eg. a gas such as helium or a liquid such as a saline solution or an oil) to and from the space 19 in counter-pulsation with the patient's heart rhythm. The membrane 18 has a shape which is, when deflated, smoothly curved and facing directly inwardly towards the lumen of the ascending aorta 10.

A relatively inelastic wrap 21 is used to hold the device 16 in the position shown on the radially outer side of the ascending aorta 10.

10 The solid line 18 illustrates the position of the membrane 18 relative to the shell 17 when fluid has been withdrawn from the space 19 and the membrane 18 has been retracted. In this position the radially outer external side wall 10e of the aorta 10 is in its normal or deflated position allowing maximum blood flow there through.

15 The phantom line 18 illustrates the position of the membrane 18 relative to the shell 17 after fluid has been introduced into the space 19 and the membrane 18 has been expanded. When the membrane 18 is expanded in this way, the aorta external wall 10e is compressed and inwardly deformed until it is close to, but not abutting, the opposite interior wall of the aorta 10r.

20 The membrane 18 is sized and positioned to compress only a portion of the circumference of the radially outer side of the ascending aorta 10. More particularly, the membrane 18 compresses only about 140 degrees of the circumference of the aorta 10.

Figs 3 to 6 show, in various orientations and views, the shape the external wall 10e of the ascending aorta 10 assumes from initial deformation (line A) through to maximum

deformation (line E). The lines A to E show the exterior of the aorta 10 flexing along a continuous line, that preferably has the shape of a conic section, which increases in length as the counter pulsation pressure applied to the artery increases. An advantage of flexing the aorta in this manner is that it is caused to compress substantially without stretching,
5 which reduces the likelihood of damage. Also the line of flexure is constantly moving so that one line of the aorta 10 is not being constantly exposed to flexural movement. Put another way, the exterior of the aorta is deformed to induce a smoothly curved ovate depression as it moves towards a position of maximum deformation (line E) of the aorta
10. In an alternative embodiment, a smoothly curved circular depression can be formed
10 in the aorta.

The lines A to E also show how the artery is progressively deformed along a line which lies in a plane running through the artery 10, that plane moving radially inwardly through the artery as the deformation increases.

The deformation described above can be caused to occur in many other different
15 ways. For example, in another embodiment, deformation can be caused by a patch device inserted into the radially outer arc of the ascending aorta. In such an embodiment, the device includes a means for applying pressure to the wall or patch which, when the wall or patch is fully invaginated, forms a shape which is a mirror image of the section of the wall or patch which as been invaginated before it was so invaginated.

20 Another embodiment of a device for assisting the functioning of a heart according to the present invention will now be described in relation to Figs. 7 to 12. Like reference numerals will be used to indicate like features used in describing to the preceding embodiment.

Fig. 7 is a schematic side view of a portion of ascending aorta 10. Line 12 is a resection line passing through the diameter of the midpoint cross section of the aorta 10 (see also Fig. 12).

Fig. 8 is a schematic view of the resected aorta 10r after cutting the aorta 10 along 5 the resection line 12 and removal of a resected portion 14.

Fig. 9 is a schematic side view of a heart assist device 16 in accordance with another embodiment of the invention. The device 16 has a relatively inelastic, preferably plastic, shell 17 and a flexible membrane 18 sealingly attached to the periphery of the shell 17. The membrane 18 defines an inflatable space 19 between it and the interior of 10 the shell 17. The shell 17 also has an inlet/outlet port 20 which is adapted for connection to a motive means that can periodically introduce, and withdraw, a fluid (eg. a gas such as helium or a liquid such as a saline solution or an oil) to and from the space 19 in counter-pulsation with the patient's heart rhythm.

Fig. 9 illustrates the position of the membrane 18 relative to the shell 17 when 15 fluid has been withdrawn from the space 19 and the membrane 18 has been retracted (18r in Figs 11 and 12). Fig. 10 illustrates the position of the membrane 18 relative to the shell 17 after fluid has been introduced into the space 19 and the membrane 18 has been expanded (18e in Figs 11 and 12). When the membrane 18 is expanded it is close to, but not abutting, the opposite interior wall of the aorta 10r.

20 The shell 17 has a peripheral edge of common shape to the opening formed in the aorta 10r after removal of the resected portion 14. This permits the device 16 to be attached to the resected aorta 10r by stitching between the periphery of the shell 17 and the periphery of the opening in the resected aorta 10r, as indicated by stitches 22 in Fig.

11.

The motive means (not shown) include a fluid reservoir and a pump means adapted to pump the fluid from, the fluid reservoir to the port 20, and thus the space 19 between the interior of the shell 17 and the flexible membrane 18, and then withdrawn 5 same, to expand (18e) and retract (18r) the membrane 18 as indicated in Figs 5 and 6. Suitable implantable fluid reservoirs and pump means are disclosed in the applicant's international PCT patent application Nos. PCT/AU00/00654 and PCT/AU02/00974, which are hereby incorporated by cross reference.

More particularly, in use, the motive means is periodically actuated to introduce 10 fluid into the space 19 in synchrony with the diastole period to reduce the interior volume of the aorta 10r and thereby provide additional pumping of the blood in the aorta 10r to assist the functioning of the heart. This introduction of fluid is alternated with periodic withdrawal of the fluid from the space 19 to allow the aorta 10r to return to its normal interior volume. As described above, the introduction of fluid expands the membrane 18 15 to be close to, but not abutting, the opposite interior wall of the aorta 10r. This maximises pumping volume without risk of the membrane 18 contacting and damaging the aorta 10r.

It will be appreciated that the heart assist device 16 includes a component, namely the membrane 18, which is blood contacting. However, the previously described disadvantages of blood contacting are minimised by the present invention as when the 20 fluid is withdrawn from the space 19 the membrane 18 is drawn into a shape substantially replicating the original (now resected) aorta wall. As a result, no eddies or pockets are introduced into the blood flow path that may disrupt blood flow when the device 16 is not activated thereby substantially reducing clot risk.

Also, if the heart recovers the device 16 can be deactivated with the membrane 18 in the retracted position (see Fig. 9 and 18r in Figs 11 and 12) allowing natural blood flow there through. In this connection, it should also be noted that heart assist devices have been proposed that function in parallel to the aorta and which receive the full 5 diverted flow of blood originally intended for the aorta. These devices can not be deactivated unlike the device according to the present invention.

Further, by installing the device 16 in a position vacated by the resected portion 14 of the aorta 10 it achieves a relatively high pumping volume for a relatively low device volume.

10 The flexible membrane 18 is preferably manufactured from a polyurethane or a polyurethane-polysiloxane block co-polymer material or other similar material, which encourages ingrowth of the passing blood cells and can eventually create a new "natural" cell lining.

15 The device according to the present invention is also particularly advantageous for use in patients whose aortas have become diseased as the device can be implanted in place of the resected damaged section.

A further embodiment of the device for assisting the functioning of a heart according to the present invention will now be described in relation to Figs. 13 to 16. Like reference numerals will be used to indicate like features used in describing to the 20 preceding embodiment. This embodiment is particularly suitable for use in patients having a naturally small aorta or an aorta that has shrunk through heart disease or the like.

Fig. 13 is a schematic cross sectional end view of a reduced diameter resected

aorta 10r showing resection line 12 and resected portion 14. The periphery of the opening formed by removing the resected portion 14 is denoted 24 in Fig. 15. Fig. 14 shows the resected aorta 10r after its included angle α has been increased to $\alpha+$ so as to open or stretch out the opening 24 in the aorta 10r. Such stretching allows the attachment of a heart assist device 16 of a similar size to that used in a healthy aorta. In this way, the effective cross section of the aorta available for pumping by the membrane 18 can be increased. For example, from about 707mm² at an original diameter of 30mm to about 1257mm² at a stretched diameter of 40mm. This results in a corresponding increase in the pumping volume of the aorta 10r.

10 Fig 17 is a schematic side view of an ascending aorta 10 showing an alternatively positioned resection line 12. In this form, the resection line 12 is angled towards the top of the aorta 10 to resect the upper, radially outer arc of the aorta 10.

15 A further embodiment of a device for assisting the functioning of a heart according to the present invention will now be described in relation to Fig 18. Like reference numerals will be used to indicate like features used in describing to the preceding embodiments.

In Fig 18 the heart assist device is a patch device 16 attachable to the ends of the aorta 10, at stitches 22, formed by removing a length of the aorta. The patch device 10 is in the general shape of a truncated toroid with an externally facing hump that forms the 20 inflatable space 19. The membrane 18 is attached to the patch device 16 about the periphery of the hump. The hump is disposed external to a line on the radially outer side, or passing through, the diameter of the mid point cross section of the aorta 10.

The flexible membrane 18 substantially replicates the shape of the interior of the

hump when the fluid is withdrawn from the space 19. The membrane 18, when the fluid is introduced into the space 19, is expanded close to, but not abutting, the adjacent interior wall of the aorta, as is shown in phantom line.

Whilst the above embodiments have been described in relation to compressing the 5 radially outer wall of the aorta, it would be appreciated by a person skilled in the art that other portions of the aorta can be deformed or other arteries can be deformed to assist in heart functions.

The heart assist devices described above are suitable for short and/or long term treatment for heart failure and/or myocardial ischemia.

10 It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

The claims defining the invention are as follows:

1. A method of providing counter-pulsation heart assistance, the method
5 comprising:

installing a heart assist device on the ascending aorta of a patient, said heart assist device being capable of exerting compressive force on the outer wall of the aorta and extending around a portion of the circumference of the aorta; and

10 causing said heart assist device to cyclically compress a portion of the circumference of the aorta, such that the aorta is caused to flex along a continuous line which increases in length as the compressive force applied to the aorta increases.

2. The method as claimed in claim 1, wherein said heart assist device is a non-inflatable mechanical device.

15

3. The method as claimed in claim 2, wherein said mechanical device is rigid.

4. The method as claimed in claim 3, wherein said rigid device is adapted to move along a linear path or along an arcuate path.

20

5. The method as claimed in claim 4, wherein said rigid device moves at a right angle to the axis of the aorta if the portion of the artery contacted by the rigid device is straight or at a right angle to a tangent of a curved portion if the portion of the aorta contacted by the rigid device is curved.

25

6. The method as claimed in claim 1, wherein said heart assist device defines a membrane which in whole or in part comprises a chamber, said chamber being capable of being inflated and deflated, said chamber being configured such that when said chamber is deflated, the membrane is substantially smoothly curved, and said membrane having a 30 concave surface when it is deflated such that the concave surface faces inwardly toward the lumen of the aorta.

7. The method as claimed in claim 6, in which said membrane is substantially inelastic.

8. The method as claimed in claim 6, wherein said membrane is substantially elastic.

5 9. The method as claimed in any one of the preceding claims, wherein the radially outer surface of the aorta is compressed.

10 10. The method as claimed in any one of the preceding claims, wherein said aorta is compressed to create a curved ovate depression.

11. The method as claimed in claim 6, wherein said membrane is sealingly attached to a shell such that said chamber comprises the space between said shell and said membrane.

15 12. The method as claimed in any one of the preceding claims, wherein the aorta is compressed through not more than 180 degrees of its circumference.

13. The method as claimed in claim 12, wherein said aorta is compressed through not more than 160 degrees of its circumference.

20 14. The method as claimed in claim 13, wherein said aorta is compressed through not more than 140 degrees of its circumference.

25 15. The method as claimed in claim 14, wherein said aorta is compressed through 100 to 140 degrees of its circumference.

16. The method as claimed in any one of the preceding claims, wherein, when fully invaginated by said heart assist device, the invaginated portion of said wall is the mirror image of said wall when no compressive force is exerted.

30 17. The method as claimed in any one of the preceding claims, wherein a layer of material is provided between said heart assist device and said wall.

18. The method as claimed in any one of the preceding claims, wherein said aorta is compressed substantially without bunching or stretching.

19. The method as claimed in any one of the preceding claims, wherein said compressive force causes said aorta to flex along a continuous line which increases in length as the pressure increases.

5

20. The method as claimed in claim 19, wherein said line has the shape of a conic section.

10 21. The method as claimed in any one of the preceding claims, wherein said compressive force is exerted in a direction normal to a tangent of the radially outer surface of the longitudinal curve in the aorta.

15 22. The method as claimed in claim 21, wherein said compressive force causes said aorta to be progressively deformed along a line in a plane running through said aorta, which plane moves radially inwardly.

23. The method as claimed in any one of the preceding claims, wherein access to the ascending aorta is achieved by a sternotomy.

20 24. A method of providing counter-pulsation heart assistance, the method comprising:

installing an inflatable heart assist device on the aorta of a patient, said heart assist device being capable of exerting compressive force on the outer wall of the aorta and extending around a portion of the circumference of the aorta;

25 periodically introducing fluid to inflate said heart assist device in synchrony with the diastolic period of the heart to reduce the interior volume of the aorta, such that the aorta is caused to flex along a continuous line which increases in length as the compressive force applied to the aorta increases;

deflating said heart assist device; and

30 alternating periods of inflation with periods of deflation to periodically deflate the heart assist device in synchrony with the commencement of the systolic period of the heart, thereby allowing the portion of the aorta adjacent to said heart assist device to periodically return to normal interior volume.

25. The method as claimed in claim 24, wherein said heart assist device comprises a patch.

26. The method as claimed in claim 25, wherein said patch is provided with a
5 flexible membrane sealingly attached to at least part of the interior of the patch thereby forming an inflatable space adjacent to the interior of the patch device which inflatable space is periodically inflated and deflated.

27. The method as claimed in claim 24, wherein said heart assist device comprises
10 an inflatable member located adjacent to the outer wall of the aorta.

28. A method of providing counter-pulsation heart assistance, the method comprising:

15 installing a heart assist device on the descending aorta of a patient, said heart assist device being capable of exerting compressive force on the outer wall of the aorta and extending around a portion of the circumference of the aorta; and

causing said heart assist device to cyclically compress a portion of the circumference of the aorta, such that the aorta is caused to flex along a continuous line which increases in length as the compressive force applied to the aorta increases.

20 29. The method as claimed in claim 28, wherein said aorta is compressed to produce a smoothly curved circular depression.

30. The method as claimed in claim 28 or 29, wherein access to the descending aorta
25 is achieved by a thoracotomy.

31. A heart assist device which includes aorta deformation means to apply a counter-pulsation to an artery in the vasculature of a patient, characterized in that the deformation means applies a deforming force to the exterior of the artery such that the artery is caused
30 to flex along a continuous line which increases in length as the counterpulsation pressure applied to the artery increases.

32. The device as claimed in claim 31, wherein the line has the shape of a conic section.

33. A method of providing counter-pulsation heart assistance, the method substantially as described herein with reference to any one of the embodiments shown in the accompanying drawings.

5

Dated 1 May, 2008
Sunshine Heart Company Pty Ltd
Patent Attorneys for the Applicant
SPRUSON & FERGUSON

10

1/7

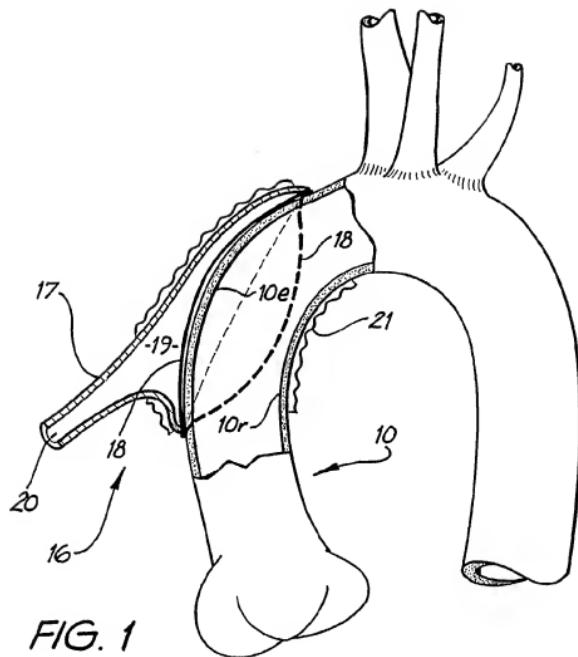


FIG. 1

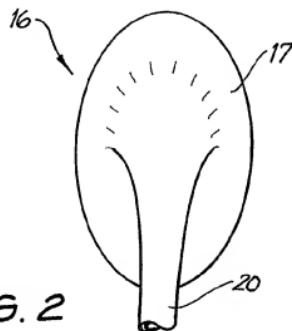
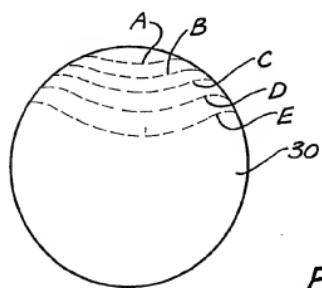
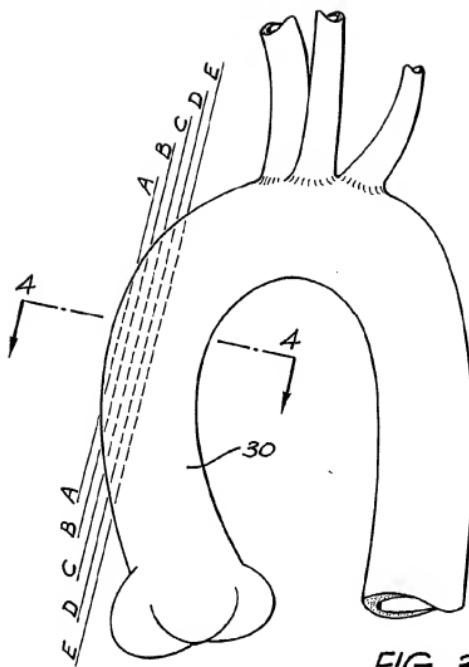


FIG. 2

2/7



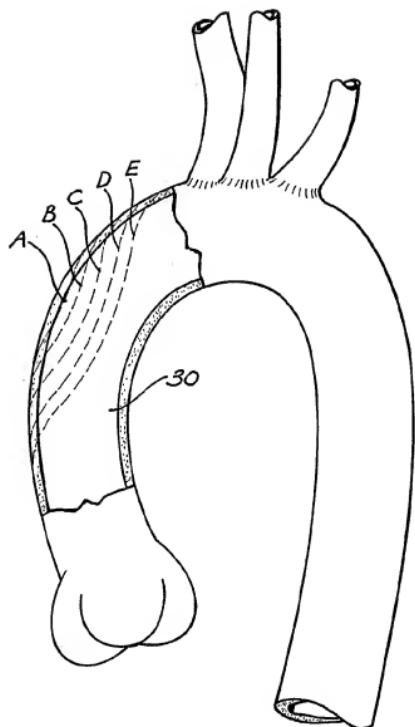


FIG. 5

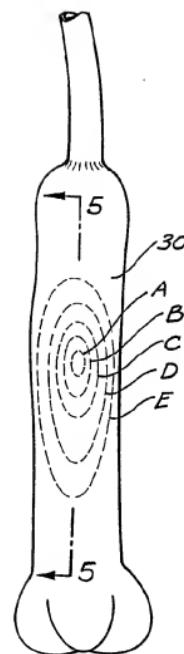


FIG. 6

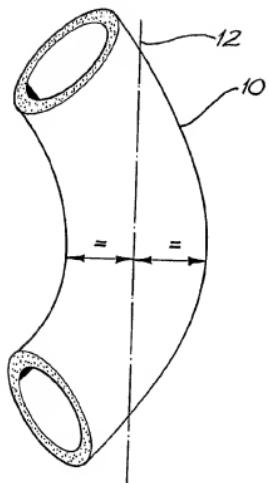


FIG. 7

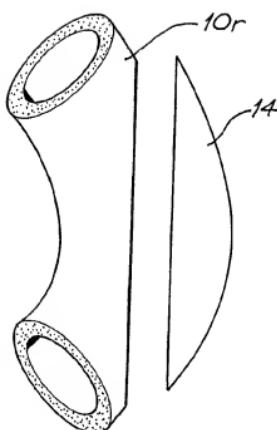


FIG. 8

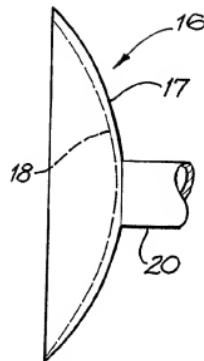


FIG. 9

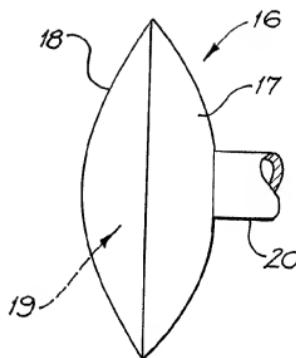


FIG. 10

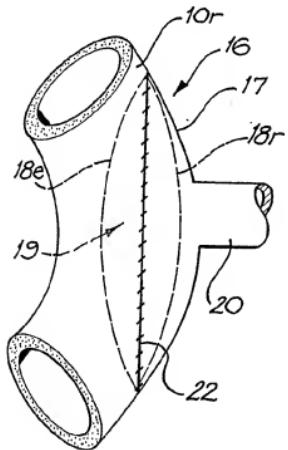


FIG. 11

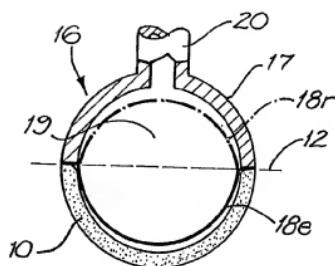


FIG. 12

6/7

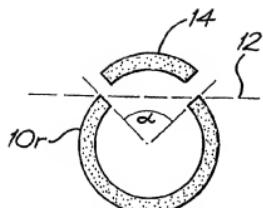


FIG. 13

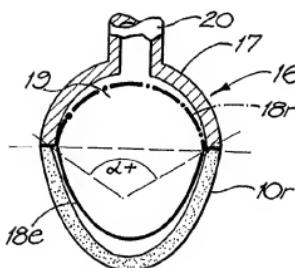


FIG. 14

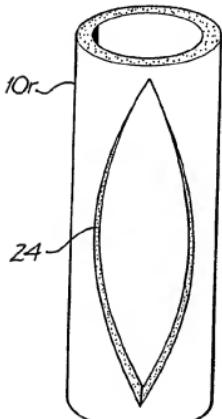


FIG. 15

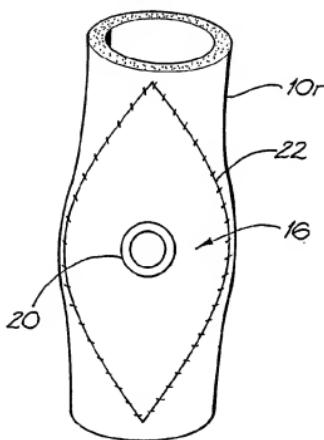


FIG. 16

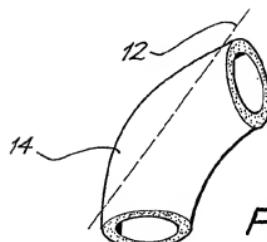


FIG. 17

7/7

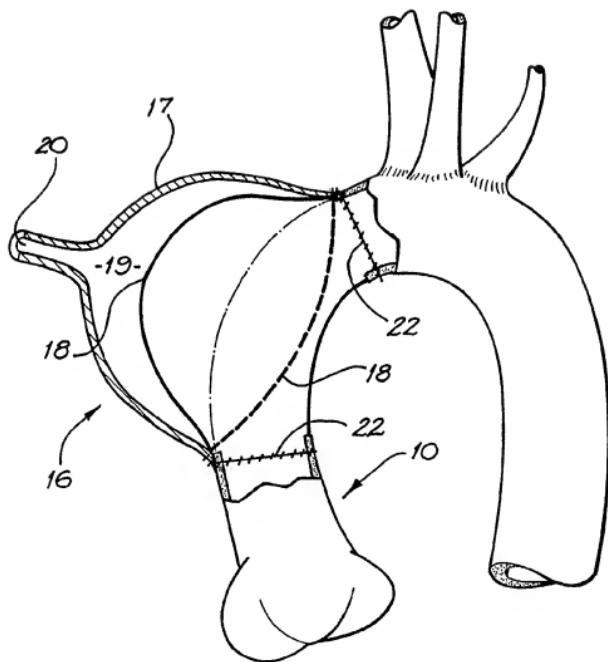


FIG. 18